

### **REMARKS**

The Office Action mailed June 16, 2003 has been reviewed and the comments of the U.S. Patent and Trademark Office have been considered. Claims 1-28 are pending. Claims 6-8, 13-18, and 20-27 are withdrawn. Claim 1 has been amended to clarify the present invention. Claim 28 has been added. Reconsideration of the grounds of rejection is respectfully requested in view of the amendments and remarks herein.

#### **Rejection Under 35 U.S.C. §102(b)**

Claims 1-5 and 12 are rejected under 35 U.S.C. §102(b) as being clearly anticipated by JP 06-305901 ("JP '901"). Applicants respectfully traverse this rejection.

JP '901 discloses a perfusate consisting of perfluorocarbon, glucose, which is a simple sugar, insulin, allopurinol, superoxide dismutase reacted with polyethylene glycol, adenosine, dexamethasone, hydroxyethyl starch, sodium ions, potassium ions and salt ions. However, JP '901 does not disclose a perfusate with a complex sugar, as required in amended claim 1. Therefore, in the absence of the complex sugar, claim 1 is clearly not anticipated by JP '901.

Claims 1-4, 9, 12, and 19 are rejected under 35 U.S.C. §102(b) as being clearly anticipated by Caldwell-Kenkel et al. in light of U.S. Patent 4,879,283 ("283 patent"). Applicants also respectfully traverse this rejection.

The '283 patent discloses a preservation solution, known as the UW solution, comprising 100 mmol potassium lactobionate, 25 mmol  $\text{KH}_2\text{PO}_4$ , 5 mmol  $\text{MgSO}_4$ , 30 mmol raffinose, 5 mmol adenosine, 3 mmol glutathione, 100 U insulin, 0.5 mL bactrim, 8 mg dexamethasone, 1mM allopurinol and 50 g hydroxyethyl starch. The '283 patent does not disclose superoxide dismutase.

Caldwell-Kenkel et al. disclose the UW solution with antioxidants, such as superoxide dismutase, but teach against the use of these antioxidants. Caldwell-Kenkel et al. disclose that the superoxide dismutase and allopurinol added to the UW solution did not reduce cell killing and did not improve cell viability in users. Caldwell-Kenkel et al. further disclose that oxygen free radical formation did not lead to injury to cells after reperfusion of livers; thus, Caldwell-Kenkel et al. also teach against the use of oxygen free radical scavengers in the UW solution. Therefore, Caldwell-Kenkel et al. in light of the '283 patent teach against the use of superoxide dismutase in a perfusion solution.

For reasons discussed above, the rejections under 35 U.S.C. §102(b) should be withdrawn.

Rejection under 35 U.S.C. §103

Claims 1-4, 9-12 and 19 are rejected under 35 U.S.C. §103 as being obvious over Caldwell-Kenkel et al. in combination with U.S. Patent 4,798,824 ("824 patent") or SU 1074471. The Examiner states that SU 1074471 discloses the inclusion of 35-45 U/L insulin in a solution for kidney preservation and the '824 patent discloses the use of 40 U/ml insulin in a solution for kidney preservation.

As discussed above, Caldwell-Kenkel et al. teach away from the use of superoxide dismutase in the cold storage solution of the present invention. In addition, the insulin concentrations disclosed in SU1074471 and the '824 patent are for entirely different solutions. Neither reference discloses that the effect of the addition of insulin and the resulting properties of the solutions disclosed in the references will be the same as in the cold storage solution of the present invention. Therefore, the rejection of claims 1-4, 9-12 and 19 under 35 U.S.C. §103 should be withdrawn.

**CONCLUSION**

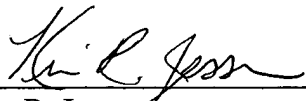
In view of the foregoing amendments and remarks, it is submitted that pending claims 1-5, 9-11, 19 and 28 are in condition for allowance. Accordingly, reconsideration and allowance of the pending claims are requested.

Furthermore, the Applicants submit that no new matter has been introduced into the amendments presented herein. Accordingly, reconsideration of the rejections presented in the Office Action mailed June 16, 2003 and passage to allowance of all pending claims at an early date are earnestly solicited. The Examiner is invited to contact the undersigned at 215-963-4753 to discuss any matter concerning this Application.

**Except** for issue fees payable under 37 C.F.R. §1.18, the Commissioner is hereby authorized by this paper to charge any additional fees during the entire pendency of this Application including fees due under 37 C.F.R. §§1.16 and 1.17 which may be required, including any required extension of time fees, or credit any overpayment to Deposit Account No. **50-0310**.

Respectfully submitted,

December 16, 2003  
Date

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